

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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30 DEC 2003

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PCT

WRITTEN OPINION
(PCT Rule 66)

Date of mailing
(day/month/year)

22.12.2003

Applicant's or agent's file reference
03/103 PCT

REPLY DUE : **within 3 month(s)**
from the above date of mailing

International application No.
PCT/EP 03/03984

International filing date (day/month/year)
16.04.2003

Priority date (day/month/year)
16.04.2002

International Patent Classification (IPC) or both national classification and IPC
C12Q1/70

Applicant
DOT DIAGNOSTICS B.V. et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the International preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 16.08.2004

Name and mailing address of the international preliminary examining authority:



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WRITTEN OPINIONInternational application No. **PCT/EP 03/03984****I. Basis of the opinion**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-16 as originally filed

Claims, Numbers

1-5 as originally filed

Drawings, Sheets

1/3-3/3 as originally filed

Sequence listing part of the description, pages:

1-18, as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of International preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

WRITTEN OPINION

International application No. **PCT/EP 03/03984**

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4-5
Inventive step (IS)	Claims	1-5
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

ITEM V:

Reference is made to the following documents:

- D1: WO 01 68915 A (PARK T.-S. ET AL.), 20 September 2001;
- D2: WO 02 26377 A (BECKMAN COULTER INC), 4 April 2002;
- D3: WO 02 02794 A (CAPITAL BIOCHIP COMPANY LTD), 10 January 2002;
- D4: JOURNAL OF GENERAL VIROLOGY, vol. 75, no. 5, 1 May 1994, pages 1149-1156, (SHAMANIN V. ET AL.), ISSN: 0022-1317;
- D5: MOLECULAR AND CELLULAR PROBES, vol. 13, no. 1, February 1999, pages 9-21, (HARNISH D.G. ET AL.), ISSN: 0890-8508.

1. NOVELTY

Claims 4-5 do not meet the requirements of Article 33(2) PCT for the following reasons:

Due to the broadness of present **claims 4-5**, the subject-matter of said claims is not novel in the sense of Article 33(2) PCT, because kits comprising a "device suitable for carrying out the detection method [...] of claims 1-3" and "a number of primer sets" as well as the additional features of said claims are disclosed in documents D1 (abstract; examples 1-4; claim 1), D2 (abstract; claim 1), and D3 (abstract; claims 1 and 22). It is noted that primers for the amplification of the HPV E1 gene are not a feature of present claims 4-5.

2. INVENTIVE STEP

Furthermore, of the present application do not appear to meet the requirements of Article 33(3) PCT for the following reasons:

- 2.1 Document D1, which is considered to represent the closest prior art, discloses a detection method for HPV using a microarray with various HPV-specific capture probes. Compared to said prior art detection method, the subject-matter of present claim 1 differs only in that the E1 gene of HPV is amplified and labelled

(whereas E1 is not explicitly mentioned in D1). Since, however, there appears to be no specific advantage associated with the use of the E1 gene for HPV detection, and since, in addition, the use of primers having conserved or consensus sequences of the E1 gene in HPV detection methods is well known (see, for example, documents D4 and D5), the involvement of an inventive step (Article 33(3) PCT) cannot be acknowledged for said claim.

- 2.2 The dependent claims 2-3 do not contain any features which, in combination with the features of claim 1 to which they refer, meet the requirements of the PCT with respect to inventive step, because the additional features of said claims are also known from D1 (see the above-cited passages).

3. INDUSTRIAL APPLICABILITY

The subject-matter of claims 1-5 appears to be industrially applicable in the sense of Article 33(4) PCT.

FURTHER COMMENTS:

- a) New claims to be filed should take account of all of the above comments.
- b) Amendments should be filed by way of replacement pages.
- c) In the reply, those parts of the application as originally filed which form a basis for the amendment should be indicated (Article 34(2)(b) PCT; Rule 66.8(a) PCT). In the absence of such indications, the amendments may be disregarded when issuing the International Preliminary Examination Report.